

each tablet may not be safely used for such purposes without special dietary controls and specific therapy under medical supervision;

Section 502 (f) (1), the labeling of the tablets failed to bear adequate directions for use;

Section 502 (f) (2), the labeling of the tablets failed to bear adequate warnings against use in those pathological conditions where their use may be dangerous to health, in such manner and form as are necessary for the protection of the user;

Section 502 (j), the tablets were dangerous to health when used in the dosage and with the frequency and duration recommended in the labeling. (The labeling suggested that the tablets be taken daily for a period up to 6 months in a dosage providing 10 milligrams of methylandrostenediol per day);

Section 503 (b) (1), the tablets, while being held for sale, were dispensed by the defendant without a prescription therefor from a practitioner licensed by law to administer the tablets; and,

Section 503 (b) (4), the tablets were subject to paragraph (1) of subsection (b) of Section 503 of the Act, and their label did not bear at all times prior to the dispensing of the tablets by the defendant the statement "Caution: Federal law prohibits dispensing without prescription."

**DISPOSITION:** March 10, 1954. The defendant having consented to the entry of a decree, the court entered a decree of permanent injunction enjoining the defendant from the acts complained of.

#### **VIOLATIVE SALES OF PRESCRIPTION DRUGS\***

**4382. Misbranding of amphetamine hydrochloride tablets. U. S. v. Clement S. Marczak (Polonia Pharmacy). Plea of not guilty. Tried to the court. Verdict of guilty. Fine of \$2,000, plus costs, on counts 1 and 2 of information; imposition of fines on remaining 2 counts suspended. Sentence of 1 year in jail imposed on all counts and suspended. Defendant placed on probation for 2 years. (F. D. C. No. 34824. Sample Nos. 8897-L to 8900-L, incl.)**

**INFORMATION FILED:** June 4, 1953, Northern District of Indiana, against Clement S. Marczak, trading as Polonia Pharmacy, Hammond, Ind.

**NATURE OF CHARGE:** On or about July 27 and August 3, 7, and 27, 1952, while a number of *amphetamine hydrochloride tablets* were being held for sale at the Polonia Pharmacy, after shipment in interstate commerce, the defendant caused various quantities of the tablets to be dispensed without a prescription from a practitioner licensed by law to administer such drug. Such acts of dispensing were contrary to Section 503 (b) (1), and resulted in the dispensed drug being misbranded while held for sale.

**DISPOSITION:** The defendant having entered a plea of not guilty, the case came on for trial before the court without a jury on January 29, 1954; and, at the conclusion of the trial on the same day, the court rendered a verdict of guilty. On May 7, 1954, the court fined the defendant \$1,000, plus costs, on each of counts 1 and 2 and suspended the imposition of fines on the remaining 2 counts of the information. The court also imposed a jail sentence of 1 year on all counts, but suspended this sentence and placed the defendant on probation for 2 years.

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\*See also No. 4381.